

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

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human.research@med.navy.mil

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Comment

HRPP: Going Purple?

The Fall *Research Protections Update* reported on two initiatives that accent the DON Human Research Protection Program's (HRPP) links with the human research protection programs of the other Services and DoD agencies: the extension of DON HRPP's PROMIS IT system throughout DoD and innovations for training to comply fully with the new Defense Department minimum education requirements framework (MERF).

Since then, the DON HRPP staff has been working on an initial draft of a comprehensive revision of the DON instruction that defines the program.

The retooled instruction will be exhaustively reviewed and released as SECNAVINST 3900.39E when signed by the Secretary of the Navy.

These initiatives together represent increasing engagement of DON's human research protection efforts with those throughout DoD.

The MERF, for example, mandates development of several new DON training modules and, as Sandy Sanford pointed out in our last issue, significant modification of most of the others for training of new HRPP staff members.

PROMIS may be adopted by the Army and Air Force, at least by non-medical organizations, and now is

being looked at as the technology baseline for a future DoD-wide HRPP system.

The new DON instruction is expected to implement the DoD Instruction 3216.02, approved late last year, which lays out DoD HRPP policy.

This trend isn't new—the Service HRPPs have been working closely together since 2006. At that time the BioSystems directorate of the Office of the Director, Defense Research & Engineering, now the Assistant Secretary of Defense for Research & Engineering (ASD [R&E]), which oversees DoD HRP policy, led an effort to “harmonize” many DoD HRPP documents, with participation from all the Services and the agency stakeholders.

The Services and agencies then collaborated in the rewrite of DoD's HRPP directive 3216.2 as the current DoD instruction. They now are working to harmonize their individual HRPP instructions, as well as with the DoDI.

The shift to a “purple” DoD HRPP may continue, as the Defense Department, with strong support from Congress, moves to consolidate the Services' medical commands in a joint Defense Health Agency.

The change for some HRPP-related programs may be even wider

and not limited to the DoD: the Department of Veterans Affairs may acquire PROMIS, and other non-DoD agencies may be interested in the system.

Also buttressing the case for PROMIS: a December 2011 report issued by the Presidential Commission for the Study of Bioethical Issues that found that the government lacks a centralized database for tracking human subjects research.

The new DON instruction is yet to start through the SECNAVINST chop chain.

Also in this Issue

RADM Bruce Doll: “If humans are involved in research ... we have a responsibility to ensure through our oversight that their treatment is ethical.”

Certification for HRPP Professionals: Greater scrutiny reveals need for greater accountability

Derek Englis and Terrence Clemmons on HRPP overseas: Culture “adds a unique and complex dimension to protection for human subjects.”

Director's Notes

Standardization, Commonality Key Goals for 2013

By CAPT Alan F. Nordholm

DON HRPP enters a new year that offers considerable opportunity to excel in our mission of protecting human subjects in DON research. While the Services confront many challenges at the start of 2013, the Navy and Marine Corps will continue to conduct research in which human subjects participate. Our work is as critical as ever, especially in light of DoD-level policy changes and, no doubt, budget constraints that could well have an impact on the management of research at both medical and non-medical Commands.

To address those challenges effectively, it's critical that we—the DON HRPP staff and Commands—focus on emphasizing standardization of practices and procedures, not only within the DON, but also, whenever possible, across all the DoD Components. A key aspect of standardization now underway is the decisive revision of the SECNAVINST 3900.39D, the DON

HRPP Instruction first approved in November 2006, to an “Echo” version. The revision of the instruction parallels the efforts of the other Services in revising their own instructions and like them, will adopt policies defined in the senior HRPP policy, DoD Instruction 3216.02, which was approved in late 2011. Our goal here is to clarify and sharpen the common HRPP mission among all the Components, and to identify ways to collaborate to more effectively protect research subjects.

Two aspects of that effort are first, supporting a DoD-wide initiative to develop an electronic IRB system to help standardize practices across the Components, an effort already underway. Second, DON HRPP will conduct a worldwide “town hall” meeting for the Navy and Marine Corps that will enable HRPP staff members throughout DON to propose innovative ways to enhance standardization and commonality.

Education and Training

Certification: Opening Doors for HRPP Professionals

Department of Defense Instruction (DoDI) 3216.02 addresses the need for initial and continuing education for all personnel involved in the conduct of human subject research. The Instruction also states that “professional certification in the field of human research protection is encouraged for all DoD personnel involved in the review and oversight of research involving human subjects.”

Certification is a benchmark for standards for protecting human research subjects. It is not an endorsement or a guarantee of an individual's qualifications or performance.

Over the past 20 years, research with human subjects has evolved from investigator-led research protocols conducted at single institutions to collaborative protocols conducted at multiple institutions.

Oversight of research with human subjects also has become more complex, and recent scrutiny of human research practices, both by federal agencies and

private institutions, has revealed the need for a greater degree of individual and institutional accountability.

Who benefits from certification?

Certified human subject research professionals enjoy both a sense of professional achievement and enhanced career opportunities. Many institutions seek to hire certified persons; others support certification as an aspect of professional development. The credential was developed to promote ethical research practices and programs by ensuring that those charged with their administration have demonstrated an advanced level of knowledge, understanding, and experience.

A number of certifications of human research protections expertise are available. Two programs have been established for IRB professionals: the Certified IRB Professional (CIP), sponsored by the Council for the Certification of IRB Professionals and the Cer-

(Continued on page 6)

Leadership Interview Part I of II**Rear Admiral Doll: “Meeting Our Responsibilities to Research Subjects”**

Rear Adm. Bruce A. Doll is Commander, Naval Medical Research and Development Command/ Special Assistant to the Chief, Bureau of Medicine and Surgery for Research Protections and Director, Office of Research Protections. A graduate of Colgate University, he was awarded his Navy Reserve commission in 1981. He earned his Doctor of Dental Surgery degree at the State University of New York at Buffalo School of Dentistry. In his first Navy assignment he served as an assistant dental officer at the Naval Branch Dental Clinic, China Lake, Calif., and then as officer-in-charge, 1st



Battalion Service Support Group. From 1985 to 1987 he served as dental department head aboard USS Juneau (LPD 10). Admiral Doll served as Periodontics department head and training officer at the U. S. Naval Academy dental clinic. Later, he served as commanding officer, NR OHSU

National Naval Medical Center. He deployed as commanding officer, Navy Expeditionary Medical Unit, for Operations Enduring Freedom and Iraqi Freedom. Upon his return he served as deputy commander, Navy Medicine East and deputy chief, Navy Reserve Dental Corps. Admiral Doll also served as chief operating officer for the Rutgers University/Cleveland Clinic research consortium focusing on regenerative medicine for the Wounded Warrior. Prior to his current assignment, he was dual-hatted as the medical advisor at NATO, ACT and the Command Surgeon for U.S. Joint Forces Command.

Admiral, please describe your own priorities for the Navy’s Human Research Protection Program (DON HRPP) both on the medical and non-medical side.

DOLL: Serving at the convenience of the Surgeon General, I have an opportunity to be informed of and enforce the SECNAVINST 3900.39D [Navy HRPP Instruction] for the purposes of human research protections. There are two ways of looking at the priority I envision. The first would be within the Navy and Marine Corps, and clearly we do have the means by which to track, through DON HRPP, the processes underway in the medical and non-medical areas of the Navy.

The point is that if humans are involved in research to the degree that questions are asked to which the SECNAVINST applies, we have a responsibility to ensure through our oversight that their treatment is ethical, that there is compliance

Readiness, Force Health Protections

with current standards for whatever a particular study—and I use the word study broadly—is involved in pursuing what usually would be either along the lines of enhanced readiness, or force health protection, or related through our global health initiatives, through our NAMRUs [Naval Medical Research Units], currently in Cairo, Lima, and Hawaii.

While the NAMRUs conduct studies in host nations, that in no way relieves the individual projects of adherence to the SECNAVINST, which is the senior DON instruction by which they’re guided. Then, if you look outside the Navy, one has to be very attentive to the other Services and agencies that conduct human research, with the idea that we’re looking at what will be more efficient, for the purposes of accomplishing a certain project—whether it should be a shared project or remain within the auspices of one Service.

There are discussions ongoing about research in general, as far as what all the Services are doing, and what might appropriately be overseen by the Assistant Secretary of Defense/Health Affairs, part of that being the topic we’re talking about today,

(Continued on page 5)

Staff Focus*Derek Englis: Culture a Critical Factor in International Research*

Derek Englis, a native of Idaho Falls, Idaho, has acquired a rich background in international relations and research. He earned his B.A. at Brigham Young University (International Relations and Psychology) and an MBA with an emphasis in international business at the University of Utah. While an undergrad he lived for two years in Mexico and became fluent in Spanish. During graduate school he worked for Governor Mike Leavitt's Utah Technology Initiative and the Utah International Business Development Office.

After earning his MBA he became chief operating officer of a small technology company in Southern California before relocating to the East Coast to study counseling and work in research ethics at George Washington University. At GWU he earned his Education Specialist (Ed.S.) degree and served as an IRB analyst and research regulatory compliance coordinator for the GWU IRB. As part of



his work at GWU he audited medical and social behavioral research, and helped train the IRB and the Office of Human Research staff on federal human research protection regulation.

B. ARNWINE

He joined DON HRPP in late 2011.

DON HRPP Research Compliance Specialist Derek Englis is uniquely qualified to support the DON Commands located overseas: Naval Medical Research Unit (NAMRU)-2, now temporarily based in Hawaii, but moving next year to Singapore; NAMRU-6 in Lima, Peru; and soon NAMRU-3 in Cairo, Egypt. He and his colleagues expect to conduct a site inspection at NAMRU-3 early this year. He also acts as POC for several stateside Commands.

Englis points out that HRPP oversight for research in foreign countries offers significant challenges. SECNAVINST 3900.39D requires researchers to obtain host-country approval and host-country ethics review or local Navy IRB review with host country representation for research conducted outside the United States with human subjects who are not U.S. citizens.

For example, he says that international commands that support research in nearby countries must have both host-country approval and a host-country ethics review for the work.

In some countries, local officials may be reluctant or unwilling to affiliate with activities associated with the U.S. Department of Defense or the individual Services.

Englis adds that NAMRU-2 headquarters works

(Continued on page 5)

DON HRPP's Clemmons Also on Point for Navy-Funded International Work

In July 2008 DoD stood up its Minerva program, described as a "university-based social-science initiative" aimed at addressing social-science topic areas, including such complex areas as the role of culture in the development of political attitudes. The Minerva initiative is intended to improve DoD's social-science intellectual capital, support basic research and expertise within the social-science community, and improve DoD's relationship with that community. Since then, DON HRPP's Research Protections Specialist Terrence Clemmons has supported DON Program Officers who seek to sponsor international research conducted by universities on such topics areas as attitudes about terrorism. He provided advice about satisfying international research requirements.

Englis: Culture Critical for International Research

(Continued from page 4)

effectively with the Command's lab in Cambodia to obtain host-country ethics review for all research sponsored by the Command in that country. He says that the requirement that IRBs be composed of U.S. federal employees can also pose a challenge for overseas commands, because an understanding of local cultures and cultural sensitivities is critical in conducting IRB reviews. For example, "consent" in some cultures may have a different meaning than in the U.S., or may be given in different ways.

Englis' academic background, international work, and his experience living in Mexico helps him recognize the challenges of communicating across cultures. Working with the Utah International

Business Development Office, he helped host foreign delegations on tours of sites of the 2002 Winter Olympic games.

While completing his MBA field study for General Electric's OEC Medical Systems, he researched the Mexican health care market, conducting interviews with Mexican medical professionals in Mexico City. While at the California technology firm, he worked with international clients.

At DON HRPP, he's comfortable with his international assignments. His extensive experience has helped him recognize the importance of understanding different cultures which, he says, add a unique and complex dimension to protection for human subjects.

Doll: "Adding Value for CNO's Sailing Directions"

(Continued from page 3)

and then whether we look to combine projects and remain compliant not only with the Navy instruction, but also with the Army and Air Force instructions.

Second, in addition to what's being done with our own SECNAVINST, which is being updated and will be published again next year, we're looking at how our instruction and the instructions of the other two Services coincide or don't coincide. There's a higher level of interest in the Common Rule and the DoD Instruction [DoDI 3216.02], with which all the Services have to comply.

So it's both a doctrinal adaptation that I'm looking at; it's oversight of our current initiatives, as well as a concern to do this within a fiscally constrained environment, that we remain aware of the efficiencies and the value we can add to the CNO's [Chief of Naval Operations Adm. Jonathan Greenert's] three main sailing directions: be ready, operate forward, and warfighting first.

The medical Commands long have protected human subjects, but the non-medical community is still getting used to it. What's right for both?

DOLL: Turnover is the nature of the Services. We

constantly have new individuals coming into these communities who are very motivated to serve. It's our responsibility to educate them.



USN

Aegis destroyer Donald Cook (DDG-75) underway

There are training courses and site visits, which are inspections, but more importantly are meant to educate people on how a facility can support what may relate to those sailing directions I mentioned or to the SG's interest in readiness, force health protection, and the global health initiatives.

Part II of RADM Doll's interview will appear in the Spring 2013 issue of Research Protections Update

Certification: Opening Doors for HRPP Professionals

(Continued from page 2)

tified IRB Manager (CIM), sponsored by the National Association of IRB Managers.



USN

Rear Admiral C. Forrest Faison III, Commander, Naval Medical Center San Diego, briefing NMCS staff

The CIP exam, offered twice annually, tests knowledge of four areas: foundations and concepts of IRB practice; organizational and personnel knowledge; IRB functions and operations; and records and reports. Certification is for three years.

The CIM test, an open-book exam, may be taken over six weeks. It covers such topics as the responsibilities of a research assistant; legal consent; and retrospective chart review. Certification expires on June 30 three years from the year awarded.

Other certification programs are aimed at research coordinators, research assistants, and clinical investigators. The Clinical Research Associate monitors the administration and progress of a clinical trial on behalf of a sponsor. Candidates for CRA certification must have a college degree plus relevant experience and must recertify every two years.

Clinical Research Coordinators work for principal investigators at clinical research sites. Minimum eligibility requirements are a high school diploma or equivalent and at least two years' experience enrolling subjects, conducting subject study visits, and maintaining source documents. Recertification is required every two years.

The Certified Physician Investigator is a physician who serves as an investigator, supervises or designs clinical trials, and is responsible for the conduct of clinical trials. An M.D. or equivalent, experience, and a license are required for two-year certification.

The CRA, CRC, and CPI are sponsored by the Academy of Clinical Research Professions. See <http://www.acrpnet.org/> for more information.

A Clinical Research Professional works as a clinical researcher, research nurse, administrator, coordinator, consultant, or educator in clinical trials research. Membership in the Society of Clinical Research Associates and a combination of work experience and degree are necessary for a three-year certification.

Mr. Chris Blood Retires

As many in the DON HRPP community already are aware, we're losing a longtime stalwart in the work of protecting research subjects with the retirement of Mr. Chris Blood after more than 31 years of federal service. For the past 11 years Chris has served IRB chair for the Naval Health Research Center, devoted to fostering excellence of, as he put it, "all things IRB-related."

Chris has been one of the most thoughtful, perceptive, and forward-looking members of the DON HRPP team for all those years. He's leaving NHRC in the capable hands of IRB member and Deputy Chair Jay Heaney and alternate member Dr. Ava Conlin.